REMARKS

This Amendment is being submitted in response to the Office Action dated July 30, 2009 in the above-identified application within the three month statutory period allowed, therefore, this Amendment is being timely filed. If it is determined that any additional fee is due in connection with this filing, the Commissioner is authorized to charge said fees to Deposit Account No. 50-0552.

Claims 1 to 4, 6, 8 to 12, 15, 16 and 18 were pending for purposes of the present Office Action. It is noted that claims 12 and 15 were rejoined by the Examiner in the July 30, 2009 Office Action based on Applicants' traversal of the restriction requirement dated March 20, 2009. Claims 1, 8, 9 and 12 have been amended in the present paper. Claims 6, 10, 11 and 15 are canceled in the present paper. Claims 5, 7, 13, 14, 17 and 21 to 24 were previously canceled in response to restriction requirement dated March 20, 2009. Claims 16 and 18 were previously withdrawn from consideration. Claims 19-20 were previously canceled in a preliminary amendment dated February 13, 2006.

It is respectfully submitted that no new matter has been added by virtue of these amendments.

Reconsideration of these currently pending claims is respectfully requested.

State of the Prior Art

On page 3 of the Office Action, the Examiner alleges that the state of the prior art, specifically WO 01/56609, teaches that "a pharmaceutical composition for producing anti-epileptic agents contains a pharmaceutical agent with vitamin B6". See Office Action, page 3, full paragraph under the section heading "The State of the Prior Art". Applicants respectfully submit that the Examiner's position is not clear to Applicants because WO 01/56609 does not disclose, teach or suggest a compound where an antiepileptic drug is covalently linked to vitamin B6.

Claim Rejections under 35 U.S.C. § 112, first paragraph

Claims 1 to 4, 6, 8 to 12, and 15 were rejected under 35 U.S.C. §112, first paragraph, allegedly "because the specification, while being enabling for making compounds wherein R' represents aminobutyrate (GABA) does not reasonably provide enablement for making compounds wherein R' represents an anti-epileptic drug, anticonvulsive drug, neuroprotective drug, neurotransmitter or nootrope moiety as claimed." See Office Action, page2, eighth full paragraph through page 3, lines 1 to 3.

Applicants respectfully submit that the present application discloses the synthesis of several novel conjugates of the formula (I) wherein vitamin B6 is covalently linked to a neuroactive drug, said neuroactive drug being selected from the antiepileptic/anticonvulsive drugs GABA (for example, see Example 1, page 12 of the present application as filed), kynurenic acid (for example, see Example 2, page 15 of the present application as filed), GABA-kynurenic acid (for example, see Example 3, page 16 of the present application as filed) and phenytoin (for example, see top of page 12 of the present application as filed). Therefore, applicants respectfully submit that, based on the specifically exemplified conjugates disclosed in the present application, a person having ordinary skill in the art will be able to make other compounds in which R' represents additional antiepileptic/anticonvulsant drugs.

Although applicants believe that compounds of formula (I) of the present invention may be useful in the treatment of various neurological diseases or disorders, in order to expedite prosecution and advance of the application towards allowance, claims 1, 8, 9 and 12 have been amended to limit the claimed compounds to those where R' represents an antiepileptic drug moiety or an anticonvulsive drug moiety. Accordingly, claims 1, 8 and 12 have been amended in relevant part to recite: a compound of the formula (I) wherein "R' represents an anti-epileptic drug moiety or an anticonvulsive drug moiety". Similarly, claim 9 recites in relevant part: a "compound of the formula (I) having R' in an amount which is no greater than the maximal safe amount for a single administration of the attached anti-epileptic drug moiety or anticonvulsive drug moiety". Applicants submit that the pending claims as amended are enabled under 35 U.S.C. §112, first paragraph.

The response refers primarily to independent claims 1, 8 and 12 of the present invention, and the patentability of the dependent claims 2 to 4 and 9 follow at least for the reason of being dependent from independent claim that is patentable. Claims 6, 10, 11 and 15 were canceled in the present paper, therefore, the rejection to claims 6, 10, 11 and 15 is moot.

Reconsideration and withdrawal of the rejection under 35 USC 112, first paragraph, is respectfully requested.

Claim Rejections under 35 U.S.C. § 112, second paragraph

Claims 1, 2, 6, 8 to 11, and 12 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. See Office Action, page 6, lines 10 to 20.

Specifically, the Office Action states that: "At claims 1, 2, 8, 9, and 12, what compounds are intended by an anti-epileptic drug, anticonvulsive drug, a neuroprotective drug, and a neurotransmitter or nootrope moiety? Clarification is appreciated." See Office Action, page 6, lines 13 to 15.

In response to the Examiner's request for clarification, claims 1, 8 and 12 have been amended in relevant part to recite: a compound of the formula (I) wherein "R' represents an anti-epileptic drug moiety or an anticonvulsive drug moiety". Similarly, claim 9 recites in relevant part: a "compound of the formula (I) having R' in an amount which is no greater than the maximal safe amount for a single administration of the attached anti-epileptic drug moiety or anticonvulsive drug moiety". Antiepileptic drugs as well as anticonvulsants are well known to any person skilled in the art. Furthermore, Applicants respectfully submit that a list of exemplary antiepileptic/anticonvulsant drugs can be found on: page 6, line 2; page 11, second paragraph; and in the Table on page 8 of the present application as filed. The response refers primarily to independent claims 1, 8 and 12 of the present invention, and the patentability of the dependent claims 2 and 9 follow at least for the reason of being dependent from independent claim that is patentable.

With respect to claims 1, 8, 9 and 12, the Office Action states: "it is suggested that the term "general" should be deleted. See Office Action, page 6, lines 16 to 17. In response, claims 1, 8, 9 and 12 have been amended to delete the word "general" as suggested by the Examiner.

With respect to claims 6 and 10, the Office Action states: "Claims 6 and 10 depend upon canceled claim 5. Correction is appreciated". See Office Action, page 6, lines 18. In response, claims 6 and 10 have been canceled as per the Examiner's request. Similarly, Applicants have also canceled claim 11, which was dependent on claim 10.

With respect to claims 1, 8 and 12, the Office Action states: "it is suggested that the phrase "and salts" should be written in the alternative. See Office Action, page 6, lines 19 to 20. In response, claims 1, 8 and 12 have been amended without prejudice to replace the phrase "and pharmaceutically acceptable salts" with the phrase "or pharmaceutically acceptable salts".

In view of the above, reconsideration and withdrawal of the rejection under 35 USC 112, second paragraph, is respectfully requested.

Rejection of the Claims under 35 U.S.C. § 102(b)

Claims 1 to 4, 6, 8 to 12, and 15 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Dolina et al. (Epilepsia, 34(1): 33-42 (1993)).

Claims 1, 8 and 12 have been amended in relevant part to recite: a compound of the formula (I) wherein "R' represents an anti-epileptic drug moiety or an anticonvulsive drug moiety; and R is selected from the group consisting of $-CH_2OH$, -CHO and $-CH_2NH_2$; or pharmaceutically acceptable salts thereof." Similarly, claim 9 recites in relevant part: a "compound of the formula (I) having R' in an amount which is no greater than the maximal safe amount for a single administration of the attached anti-epileptic drug moiety or anticonvulsive drug moiety".

Applicants submit that the Dolina et al. publication describes genetically-based epilepsy-prone (EP) and epilepsy-resistant (ER) mice. The Dolina et al. publication discloses the effects of pyridoxine treatment on the regional brain levels of putative neurotransmitter amino acids.

Applicant's respectfully submit that the Dolina et al. publication does not show or teach mixtures or compounds of the formula (I) wherein "R' represents an anti-epileptic drug moiety or an anticonvulsive drug moiety; and R is selected from the group consisting of $-CH_2OH$, -CHO and $-CH_2NH_2$; or pharmaceutically acceptable salts thereof" as recited in claims 1, 8 and 12 of the present application. Similarly, Dolina does not show or teach a "compound of the formula (I) having R' in an amount which is no greater than the maximal safe amount for a single administration of the attached anti-epileptic drug moiety or anticonvulsive drug moiety" as recited in claim 9 of the present invention.

Therefore, Dolina et al. discloses the effects of pyridoxine treatment on the regional brain levels of putative neurotransmitter amino acids. Dolina does not teach or show a compound of the formula (I) wherein "R' represents an anti-epileptic drug moiety or an anticonvulsive drug moiety; and R is selected from the group consisting of $-CH_2OH$, -CHO and $-CH_2NH_2$; or pharmaceutically acceptable salts thereof" as recited in claims 1, 8 and 12 of the present invention. Because the Dolina et al. publication does not show or teach each and every element of the current claims, the Dolina et al. publication cannot anticipate the claimed invention.

The response refers primarily to independent claims 1, 8 and 12 of the present invention, and the patentability of the dependent claims 2 to 4 and 9 follow at least for the reason of being dependent from independent claim that is patentable. Claims 6, 10, 11 and 15 were canceled in the present paper, therefore, the rejection to claims 6, 10, 11 and 15 is moot.

Reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) to Dolina et al. (Epilepsia, 34(1): 33-42 (1993)) is respectfully requested.

Claims 1 to 3, 6, 8 to 12, and 15 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Dakshinamurti et al. (Biochem. Biophys. Acta 1647: 225-229 (2003)).

As noted above, claims 1, 8 and 12 have been amended in relevant part to recite: a compound of the formula (I) wherein "R' represents an anti-epileptic drug moiety or an anticonvulsive drug moiety; and R is selected from the group consisting of $-CH_2OH$, -CHO and $-CH_2NH_2$; or pharmaceutically acceptable salts thereof." Similarly, claim 9 recites in relevant part: a "compound of the formula (I) having R' in an amount which is no greater than the maximal safe amount for a single administration of the attached anti-epileptic drug moiety or anticonvulsive drug moiety".

Applicants respectfully submit that the Dakshinamurti et al. publication discloses the neuroprotective actions of pyriodoxine in mice treated with the neurotoxin domoic acid, and compares the effectiveness of pyriodoxine to the effectiveness of several known antiepileptic drugs with respect to preventing domoic acid-induced seizure activity. The Dakshinamurti et al. publication does not disclose mixtures comprising vitamin B6 derivatives and a drug. Specifically, the Dakshinamurti et al. publication does not show or teach a conjugate compound of the formula (I) wherein "R' represents an anti-epileptic drug moiety or an anticonvulsive drug moiety; and R is selected from the group consisting of $-CH_2OH$, -CHO and $-CH_2NH_2$; or pharmaceutically acceptable salts thereof" as recited in claims 1, 8 and 12 of the present application. Similarly, the Dakshinamurti et al. publication does not show or teach a "compound of the formula (I) having R' in an amount which is no greater than the maximal safe amount for a single administration of the attached anti-epileptic drug moiety or anticonvulsive drug moiety" as recited in claim 9 of the present invention.

Therefore, the Dakshinamurti et al. publication discloses the neuroprotective actions of pyriodoxine in mice treated with the neurotoxin domoic acid, and compares the effectiveness of pyriodoxine to the effectiveness of several known antiepileptic drugs with respect to preventing domoic acid-induced seizure activity. Dakshinamurti does not teach or show a compound of the formula (I) wherein "R' represents an anti-epileptic drug moiety or an anticonvulsive drug moiety; and R is selected from the group consisting of $-CH_2OH$, -CHO and $-CH_2NH_2$; or

pharmaceutically acceptable salts thereof" as recited in claims 1, 8 and 12 of the present invention. Because the Dakshinamurti et al. publication does not describe each and every element of the current claims, the Dakshinamurti et al. publication cannot anticipate the claimed invention.

The response refers primarily to independent claims 1, 8 and 12 of the present invention, and the patentability of the dependent claims 2, 3 and 9 follow at least for the reason of being dependent from independent claim that is patentable. Claims 6, 10, 11 and 15 were canceled in the present paper, therefore, the rejection to claims 6, 10, 11 and 15 is moot.

Reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) to Dakshinamurti et al. (Biochem. Biophys. Acta 1647: 225-229 (2003)) is respectfully requested.

Conclusion

This Response is being submitted in response to the Office Action dated July 30, 2009 in the above-identified application. As this Response is being submitted within the shortened statutory period for reply of three (3) months, this Response is being timely filed and no fees are believed due at this time. If it is determined that any additional fee is due in connection with this filing, the Commissioner is authorized to charge said fees to Deposit Account No. 50-0552.

An early and favorable action on the merits is earnestly requested.

Respectfully submitted,
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